

At any point in time a volunteer may opt-out by removing their name from the database of volunteers. Figure 4 is an exemplary Opt-Out form display screen. The volunteer is preferably asked to enter their first name, last name, and date of birth. Any information may be requested so long as the particular volunteer to be removed can be properly identified. Additional information may be used to properly identify the volunteer, such as the maiden name of the volunteer's mother. It is contemplated that the most basic information, e.g., the full name and date of birth of the volunteer, may be initially requested and that additional information will be solicited only if the database identifies multiple matches from the database of volunteers. In an alternative embodiment, the volunteer when registering with the service is assigned a unique identification number that may be subsequently entered by the volunteer when requesting to be removed from the list of potential candidates. In this alternative embodiment, if the volunteer could not recall their identification number, other means for identifying the volunteer as discussed above may be employed.

The description at page 7, lines 5 - 17 of the original specification indicates that a volunteer begins the opt out by entering identifying information (for example, “their first name, last name, and date of birth” or “(any information ... so long as the particular volunteer to be removed can be properly identified”). The description goes on to indicate that “additional information will be solicited only if the database identifies multiple matches from the database of volunteers.” By clear implication, no additional information will be requested (and the opt-out procedure will be completed) if the database identifies a single match between the entered identifying information and identifying information in the database of volunteers. Applicant submits that identifying information in the database of volunteers is commonly understood to be stored in the database of volunteers. Applicant further submits that a match found between entered information and stored information in a database it is commonly understood to result from the execution of a comparison operation.

Accordingly, Applicant respectfully submits that the description at page 7, lines 5 - 17 of the original specification provides adequate support for the claim step in recited in claims 210, 223, 238, 245 and 249 reciting that an “individual’s registration [is withdrawn] when the comparing step

indicates a match between the transmitted personally-identifying information and the stored personally-identifying information.” Applicant therefore respectfully requests that the objection as to claims 210, 223, 238, 245 and 249 be withdrawn.

IV. Claim Rejections under 35 U.S.C. § 112

Claims 210 - 214, 223, 238, 245 - 248 and 249 - 253 are rejected under the first paragraph of 35 U.S.C. § 112 as containing subject matter which was not described in the specification in a way to reasonably convey to one skilled in the art that the inventor was in possession of his at the time the application was filed. Specifically, it appears that the rejection under the first paragraph of 35 U.S.C. § 112 is also directed to the recited claim step of “withdrawing the individual’s registration when the comparing step indicates a match between the transmitted personally-identifying information and the stored personally-identifying information” as recited in claims 210, 223, 238, 245 and 249. For the reasons presented above, Applicant respectfully submits that description at page 7, lines 5 - 17 of the original specification adequately supports this claim step, and thereby indicates that the inventor was in full possession of this claimed matter at the time the application was filed. Accordingly, Applicant respectfully requests that the rejection of claims 210 - 214, 223, 238, 245 - 248 and 249 - 253 under the first paragraph of 35 U.S.C. § 112 be withdrawn.

V. Claim Rejections under 35 U.S.C. §§ 102, 103

Claims 204 - 209, 215 - 221, 224 - 229, 231 - 236, and 239 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Publication 2002/0002474 to Michelson et al. Claims 210 - 214, 222, 223, 237, 238 and 245 - 253 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of “drkoop.com & Quintiles Launches Service to Recruit Clinical Trial Patient on the Internet,” PR Newswire, April 13, 1999 (“Newswire”). Claims 230 and 240 - 244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of U.S. Patent No. 6,171,112 to Clark (“Clark”). Applicant respectfully traverses these rejections.

In an application claiming priority under 35 U.S.C. § 119(e) from a provisional patent application, the specification of the provisional application “must ‘contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise terms,’ 35 U.S.C. § 112 ¶1, to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application.” *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002), *rehearing denied, en banc rehearing denied, New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 2002 U.S. App. LEXIS 21339 (Fed. Cir. 2002), *cert denied, New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 537 U.S. 1232 (2003). The written description component of 35 U.S.C. § 112 ¶1 asks whether one skilled in the art may sufficiently discern the claimed features of the invention directly from the specification, without resort to discovery by practicing the invention. *New Railhead Mfg., L.L.C.* at 1295, *citing Martin v. Mayer*, 823 F.2d 500, 505, (Fed. Cir. 1987) (“It is not a question of whether one skilled in the art might be able to construct the patentee’s device from the teachings of the disclosure [but] whether the application necessarily discloses that particular device.” (quoting *Jepson v. Coleman*, 50 C.C.P.A. 1051, 314 F.2d 533, 536, 136 U.S.P.Q. (BNA) 647, 649-50 (C.C.P.A. 1963), *emphasis added*)).

For the Examiner's reference, Applicant encloses a copy of Provisional Patent Application No. 60/178,634 as Exhibit A. ("the '634 Provisional"). A comparison of the '634 Provisional with Michelson is striking. The specification of the '634 Provisional is provided in 10 single-column, double-spaced pages of 12-point text, while Michelson's specification runs for nearly 19 pages in double-column, single-spaced format of 6-point text. A word count comparison

reveals about 3,000 words¹ in the specification of the '634 Provisional, which blossoms to more than 19,000 words in the specification of Michelson (an increase of more than six-fold). Most striking, while the '634 Provisional provides three figures that illustrate its specification, Michelson expands upon these three figures nearly thirty-fold by providing a total of 89 figures.

Of course, and as explained by the Court in *New Railhead Mfg., L.L.C.*, the relevant inquiry with regard to a priority claim under 35 U.S.C. § 119(e) in view of 35 U.S.C. § 112 ¶1 is not simply to compare page and figure counts, but to determine whether the specification of the provisional application conveys “with reasonable clarity to those skilled in the art that, as of the filing date sought, [that the inventors of the subject matter of the provisional application were] in possession of the invention [as described in the non-provisional application]” *New Railhead Mfg., L.L.C.* at 1295, citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991).

Applicant encloses as Exhibit B a table that compares the disclosure of Michelson, as relied upon by the Examiner in his rejection of claims 204 - 253, with the disclosure provided in the '634 Provisional. Applicant respectfully submits that, upon reviewing the table in Exhibit B, it becomes strikingly clear that the '634 Provisional fails to provide a sufficient basis for finding that the inventors of the subject matter disclosed by Michelson were in possession of the subject matter presently relied upon by the Examiner at the time of Michelson's filing of the '634 Provisional. Specifically, and for at least the reasons summarized in the table of Exhibit B, Applicant submits that subject matter in paragraphs [0010], [0095], [0097], [0099], [0113], [0114], [0165] and [0167] of Michelson as relied on by the Examiner in rejecting claims 204 - 253 is not sufficiently described in the '634 Provisional to suggest that the inventors were in possession of this subject matter at the time of filing of the '634 Provisional.

Applicant acknowledges that a related question as to the sufficiency of the '634 Provisional under 35 U.S.C. § 112 ¶1 was considered by the Board of Patent Appeals and Interferences (BPAI) in response to an appeal raised during the prosecution of Michelson. *Ex parte Michelson* (Appeal No. 2005-2501 in regard to Application No. 09/923,385, Decision on Appeal,

¹ Conservatively estimated at 300 words per page.

unpublished and non-binding) (B.P.A.I. 2006). The BPAI considered, inter alia, appellants' appeal of a claim rejection under 35 U.S.C. § 103(a) based on U.S. Patent Publication No. 2002/0099570 to Knight. Knight was applied as a reference qualifying under 35 U.S.C. § 102(e) in view of the actual filing date of Michelson. In the rejection, the Examiner asserted that the applicants were "not entitled to the provisional filing date [of the '634 Provisional] because that provisional application disclosure did not support the now claimed 'presenting a questionnaire' [limitation]." *Ex parte Michelson* at 7.

The BPAI found that there was sufficient support in the '634 Provisional to accord the filing date of the '634 Provisional to the claim term "automatically presenting a questionnaire associated with the given clinical study to the person or caregiver" *Ex parte Michelson* at 7. The Board based its decision on the following argument:

It appears reasonable to us that the cited passage from page 9 of the provisional application does provide support, albeit not *verbatim*, for "automatically presenting a questionnaire." The artisan would have understood from the system including software that supports "account sing-up, management, demographics capture, and personalization of target audiences;" from "behavioral data collection ... and specified user views" that a user is indeed inputting information that is requested of him/her, i.e., there is some type of questionnaire presented to the user in order to acquire his information. Also, since there is a "comparison of the participant profile" (it appears that a participant profile would have been collected by responses to a questionnaire) "to the trials protocol criteria," it is clear that questionnaire-entered data from a user is compared to clinical criteria

Ex parte Michelson at 10.

In reaching this decision, the BPAI appears to endorse an argument made by the appellants that claimed questionnaire would be understood by the skilled artisan as the only way in which the functionality disclosed in the '634 Provisional could be achieved:

Since appellants contend that there is no other imaginable scenario as to how the system would perform the described functionality without presenting a questionnaire to the user, and the examiner has identified no alternative interpretation of the cited passage, appellants contend that there is sufficient support in the provisional application for automatically presenting a questionnaire," as claimed.

Applicant respectfully disagrees with the BPAI decision in this instance. The ‘634

The system also includes a patient database 310. The patient database is constructed as to protect the patients' privacy, and includes information about individual patients, such as relevant clinical data, zip code of residence, and e-mail addresses. This database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data from the physician practice management systems of the physician investigators who have private practices, and through managed care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients.

Thus, and in sharp contrast to appellants assertions as to there being “no other imaginable scenario” to collect patient data other than by using a patient questionnaire, the ‘634 Provisional explicitly discloses a variety of other mechanisms for collecting patient data that are distinct from providing the patient with a patient questionnaire.²

² Given the variety of distinct mechanisms disclosed, it is curious (and somewhat telling) that appellants failed to explicitly disclose a patient questionnaire as one approach for collecting patient information.

Conclusion

Therefore, in view of the above amendments and remarks, it is respectfully requested that a Notice of Allowance as to all pending claims be issued in this case.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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